(2)

USAFSAM-TP-89-4

EVALUATION OF THE INTRAVENOUS STAT CONSTANT PRESSURE INFUSER

Rufino U. Navalta, Jr., Master Sergeant, USAF

August 1989

Interim Report for Period March 1986 - July 1988

Approved for public release; distribution is unlimited.

USAF SCHOOL OF AEROSPACE MEDICINE
Human Systems Division (AFSC)
Brooks Air Force Base, TX 78235-5301

NOTICES

This interim technical paper was submitted by personnel of the Chemical Defense Branch, Crew Technology Division, USAF School of Aerospace Medicine, Human Systems Division, AFSC, Brooks Air Force Base, Texas, under job order 7930-16-12.

When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use, or sell any patented invention that may in any way be related thereto.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.

RUFINO U. NAVALTA, JR., MSgt, USAF
Project Scientist

F. WESLEY BAUMGARDNER, Ph.D.
Chief, Chemical Defense Branch

GEORGE E. SCHWENDER, Colonel, USAF, MC, CFS
Commander

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

1a. REPORT SECURITY CLASSIFICATION: Unclassified	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION/AVAILABILITY OF REPORT: Approved for public release; distribution is unlimited.
2b. DECLASSIFICATION/DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S): USAFSAM-TP-89-4	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION: USAF School of Aerospace Medicine; 6b. OFFICE SYMBOL (If applicable): USAFSAM/VNC	7a. NAME OF MONITORING ORGANIZATION
6c. ADDRESS (City, State, and ZIP Code): Human Systems Division (AFSC), Brooks Air Force Base, TX 78235-5301	7b. ADDRESS (City, State, and ZIP Code)
8a. NAME OF FUNDING/SPONSORING ORGANIZATION: HQ, Military Airlift Command; 8b. OFFICE SYMBOL (If applicable): MAC/SGNL	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
8c. ADDRESS (City, State, and ZIP Code): Scott Air Force Base, IL 62225	10. SOURCE OF FUNDING NUMBERS

PROGRAM ELEMENT NO.	PROJECT NO.	TASK NO	WORK UNIT ACCESSION NO
62202F	7930	16	12

11. TITLE (Include Security Classification): Evaluation of the Intravenous Stat Constant Pressure Infuser

12. PERSONAL AUTHOR(S): Navalta, Rufino U., Jr.

13a. TYPE OF REPORT	13b. TIME COVERED	14. DATE OF REPORT (Year, Month, Day)	15. PAGE COUNT
Interim	FROM 86/03 TO 88/07	1989, August	8

16. SUPPLEMENTARY NOTATION

17. COSATI CODES			18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
FIELD	GROUP	SUB-GROUP	Test and evaluation; Intravenous (I.V.) bag pressor; I.V. Stat; Aeromedical evacuation.
23	01		
23	05		

19. ABSTRACT (Continue on reverse if necessary and identify by block number)

The I.V. Stat Constant Pressure Infuser is a self-contained, portable intravenous (I.V.) pump that generates a constant, safe pressure on flexible infusion bags to assure a steady flow. The source of its energy is a unique, constant force spring that continuously exerts a predetermined pressure on the flexible bag without adjustment, until it is completely empty. The force spring provides the same constant pressure on the flexible bag whether it is fully or partially infused. A special feature is that the I.V. Stat may be placed on any convenient surface near the patient. The I.V. Stat was found unacceptable for use on board aeromedical evacuation aircraft. This technical paper presents the results of the United States Air Force School of Aerospace Medicine/Chemical Defense Branch, Aeromedical Research Function evaluation of the I.V. Stat.

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT	21. ABSTRACT SECURITY CLASSIFICATION
☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT ☐ DTIC USERS	Unclassified

22a. NAME OF RESPONSIBLE INDIVIDUAL	22b. TELEPHONE (Include Area Code)	22c. OFFICE SYMBOL
Rufino U. Navalta, Jr., Master Sergeant, USAF	(512) 536-2937	USAFSAM/VNC

DD Form 1473, JUN 86 *Previous editions are obsolete.* SECURITY CLASSIFICATION OF THIS PAGE

EVALUATION OF THE
INTRAVENOUS STAT CONSTANT PRESSURE INFUSER

INTRODUCTION

Our evaluation was initiated as a result of a documented suggestion to purchase the Intravenous (I.V.) Stat Constant Pressure Infuser (I.V. Stat) instead of designing a similar unit for the 2d echelon facility and aeromedical evacuation units. The suggestion was approved at the major command level and by the United States Air Force Clinical Consultants Division. The Air Force Medical Readiness Division and the Air Force Medical Logistics Division approved the I.V. Stat with the condition that Human Systems Division (HSD) procure and evaluate the device. The Human Systems Division tasked the United States Air Force School of Aerospace Medicine/ Chemical Defense Branch to evaluate the I. V. Stat. A similar request to evaluate the device was also received from the 375th Aeromedical Airlift Wing (MAC/SGNL), Scott AFB, Illinois. This technical paper presents the results of our evaluation of the I.V. Stat, Model 250-X, manufactured by I.V. Stat Corporation, P.O. Box 961, La Jolla, CA 92038.

The I.V. Stat Constant Pressure Infuser (Fig. 1) is a self-contained, portable intravenous (I.V.) pump that generates a constant, safe pressure on flexible infusion bags to assure a steady flow. The source of its energy is a unique, constant force spring that continuously exerts a predetermined pressure on the flexible bag without adjustment , until it is completely empty. The force spring provides the same constant pressure on the flexible bag whether it is fully or partially infused. A special feature is that the I.V. Stat may be placed on any convenient surface near the patient (1). The I.V. Stat is all metal, satin anodized aluminum, and stainless steel with silicone rubber pads. It weighs 1.05 kg (2.3 lb) and is 15 cm (6 in.) wide and 46 cm (18 in.) long. The I.V. Stat can infuse a flexible I.V. bag up to 1,000 ml (cm^3). The I.V. Stat can be sterilized by steam autoclaving, gas or dry heat and is washable in hot water detergent. It doesn't require batteries or an external power supply.

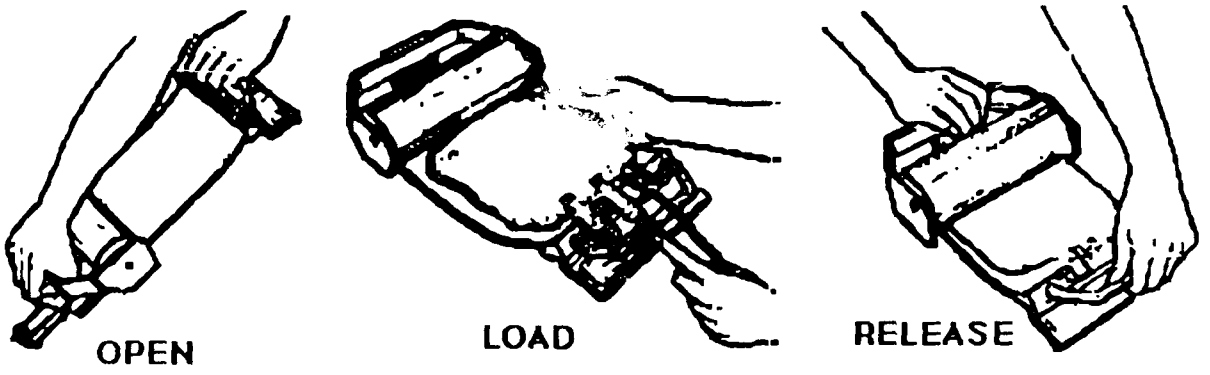

Figure 1. I.V. Stat Constant Pressure Infuser

METHODS

The Aeromedical Equipment Evaluation Laboratory (AEEL) develops test procedures that cover safety and human factors issues regarding the equipment to be tested. Specifically, a "performance check" is developed; this check is a procedure that verifies proper functioning of the equipment under various conditions. Before our evaluation, an initial inspection is performed by a biomedical equipment maintenance technician (BEMT) to verify conformance to manufacturer specifications.

When the device passes the initial inspection, it is subjected to various "referee tests" that check its performance under various anticipated operational conditions. The "referee tests" generally involve a repetition of the performance check under the specified conditions. Each "referee test" also includes any special measurements or procedures necessary due to the peculiarities of the testing conditions.

Performance Check

The I. V. Stat was prepared in accordance with manufacturer's literature. To perform this check, a 1,000 ml 0.9 % sodium chloride solution I.V. bag, Migada Emergency and Military Infusion System (EMIS) administration set, an Arm-A-Flow I.V. Flow Regulator, and an 18-gauge catheter were used. Flow was adjusted using the EMIS clamp or Arm-A-Flow and measured at the EMIS drip chamber. Pressure was measured using a Gould pressure transducer, Series P23 and Preamplifier, Model 13-461550, and recorded on a Grant Squirrel Data Logging System. Pressure was continously recorded at the I.V. bag injection port during the maximum flow test. During the other tests when the flow was adjusted for a certain rate, pressure was measured by momentarily occluding the I.V. fluid flow at a 3-way stopcock placed in-line before the catheter. For all the tests, the I. V. Stat was at a horizontal position and at the same plane as the administration set, pressure transducer, and catheter.

Initial Inspection

The following tests were performed:

1. Maximum flow.
2. Flow at 56 drops/min or 168 ml/h using EMIS.
3. Flow at 85 drops/min or 255 ml/h using EMIS and Arm-A-Flow.
4. Human factors and physical characteristics.

Altitude

The test setup was the same as in the initial testing, but with a slight change. The flow was set at 85 drops/min or 255 ml/h using the EMIS. The following recordings were taken:

- Ground level (Preflight) - 2 sets of drop rate and pressure reading, 1 min apart.

- 8,000 ft - 2 sets of drop rate and pressure reading, 1 min apart. Repeat at 5 min intervals for 40 min.

- Ground level (Postflight) - 2 sets of drop rate and pressure reading, 1 min apart.

Tests Not Performed

Electromagnetic compatibility (EMC) tests were not necessary because the I.V. Stat does not have any components that may cause electromagnetic interference. Vibration, environmental, clinical, and in-flight tests were not performed because data gathered from initial inspection and altitude chamber testing were sufficient to support our final results and recommendations.

RESULTS

The I.V. Stat has a simple design. Setup was well illustrated and explained in the operation manual of the manufacturer. However, the I. V. Stat has some design deficiencies. Pressure (41 mmHg - 55 mmHg), measured during maximum flow and when the flow was set at a certain rate, was significantly lower than the manufacturer claim of delivering a constant 70 mmHg (Fig. 2). The difference in measured pressures may be due to a different setup used by the manufacturer. As stated in the performance section of this paper, the I.V. Stat was at a horizontal position and at the same plane as the administration set, pressure transducer, and catheter. The manufacturer may have elevated the I.V. Stat above the catheter.

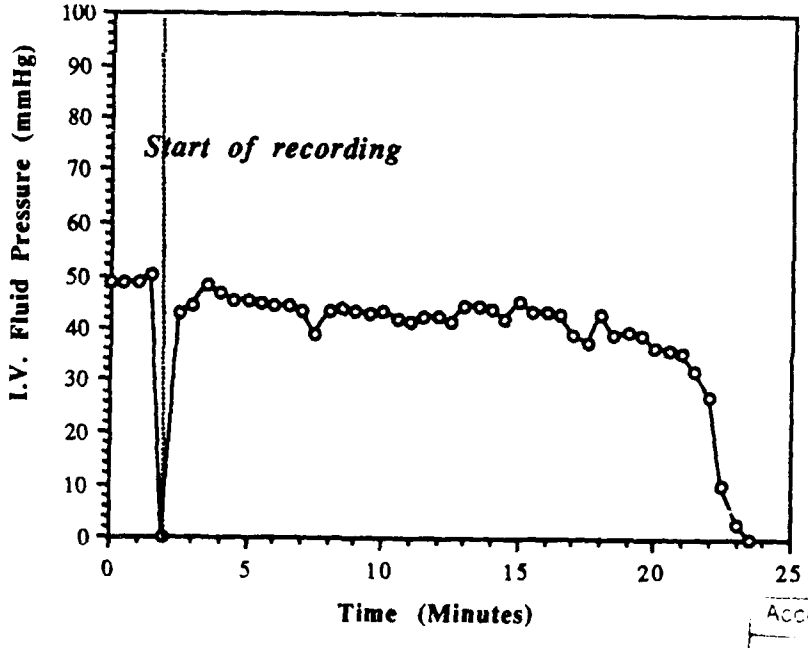

Figure 2. Maximum I.V. fluid flow.

The I.V. Stat has an automatic locking device that locks up the roller if the device is tilted more than 10 degrees, but there is no visual indication to show whether the locking mechanism is engaged or not. This disadvantage will affect litter patients on aeromedical evacuation flights using this device because the aircraft ramp for enplaning and deplaning patients is more than 10 degrees elevation. The device locked up several times during the testing for no apparent reason. The roller spring housing and silicone rubber pad can be contaminated with dirt, mud, and chemical warfare agents during field conditions.

The I.V. Stat cannot be safely mounted. The edge of the roller is thin and could cut if it were to accidentally fall on a patient or medical provider. Sharp corners of the device can potentially injure a patient or care provider. These hazards are major concerns on an aeromedical evacuation flight especially in the event of air turbulence, a "hard" landing, or a rapid decompression. A portion of the I.V. bag will not be delivered unless the roller mechanism is fully extended. However, fully extending the roller mechanism could cause the locking mechanism to get stuck and become difficult to release. Correcting this condition is an awkward procedure; the user must place the handle (end with the instructions) between the user's feet and pull up the roller mechanism handle.

CONCLUSIONS

Based on the data and observations gathered during our evaluation and testing, we concluded that the I. V. Stat is unacceptable for use in the aeromedical evacuation environment mainly for the safety reasons stated in the results section of this report.

ACKNOWLEDGMENTS

I wish to thank the following individuals for their support during the performance phase of this report:

Major Garye D. Jensen, Chief Nurse Aeromedical Research Function; 2Lt Rebecca B. Schultz, Research Biomedical Engineer; TSgt Ernest G. Roy, Biomedical Equipment Maintenance Technician; and TSgt Robert J. Van Oss, Aeromedical Evacuation Technician.

REFERENCES

1. I.V. Stat Constant Pressure Infuser, Model 250 and 250-X, User Manual. La Jolla, CA: I.V. Stat Corporation, Sep 1976.

☆ U.S. GOVERNMENT PRINTING OFFICE 1989- 761-051 9-00060